the names and addresses of all recipients of the communications not provided in accordance with paragraph (c)(11) of this section.

(13) If any required information is not immediately available, a statement as to why it is not available and when it will be submitted.

(d) If, after submitting a report under this part, a manufacturer or importer determines that the same correction or removal should be extended to additional lots or batches of the same device, the manufacturer or importer shall within 10-working days of initiating the extension of the correction or removal, amend the report by submitting an amendment citing the original report number assigned according to paragraph (c)(1) of this section, all of the information required by paragraph (c)(2), and any information required by paragraphs (c)(3) through (c)(12) of this section that is different from the information submitted in the original report. The manufacturer or importer shall also provide a statement in accordance with paragraph (c)(13) of this section for any required information that is not readily available.

(e) A report submitted by a manufacturer or importer under this section (and any release by FDA of that report or information) does not necessarily reflect a conclusion by the manufacturer, importer, or FDA that the report or information constitutes an admission that the device caused or contributed to a death or serious injury. A manufacturer or importer need not admit, and may deny, that the report or information submitted under this section constitutes an admission that the device caused or contributed to a death or serious injury.

(f) No report of correction or removal is required under this part, if a report of the correction or removal is required and has been submitted under parts 803 or 1004 of this chapter.

[62 FR 27191, May 19, 1997, as amended at 63 FR 42232, Aug. 7, 1998; 69 FR 11311, Mar. 10, 2004]

§ 806.20 Records of corrections and removals not required to be reported.

(a) Each device manufacturer or importer who initiates a correction or removal of a device that is not required to be reported to FDA under § 806.10 shall keep a record of such correction or removal.

(b) Records of corrections and removals not required to be reported to FDA under § 806.10 shall contain the following information:

(1) The brand name, common or usual name, classification, name and product code if known, and the intended use of the device.

(2) The model, catalog, or code number of the device and the manufacturing lot or serial number of the device or other identification number.

(3) A description of the event(s) giving rise to the information reported and the corrective or removal action that has been, and is expected to be taken.

(4) Justification for not reporting the correction or removal action to FDA, which shall contain conclusions and any followups, and be reviewed and evaluated by a designated person.

(5) A copy of all communications regarding the correction or removal.

(c) The manufacturer or importer shall retain records required under this section for a period of 2 years beyond the expected life of the device, even if the manufacturer or importer has ceased to manufacture or import the device. Records required to be maintained under paragraph (b) of this section must be transferred to the new manufacturer or importer of the device and maintained for the required period of time.

[62 FR 27191, May 19, 1997, as amended at 63 FR 42233, Aug. 7, 1998]

§ 806.30 FDA access to records.

Each device manufacturer or importer required under this part to maintain records and every person who is in charge or custody of such records shall, upon request of an officer or employee designated by FDA and under section 704(e) of the act, permit such officer or employee at all reasonable times to have access to, and to copy and verify, such records and reports.

[63 FR 42233, Aug. 7, 1998]

§ 806.40 Public availability of reports.

(a) Any report submitted under this part is available for public disclosure

in accordance with part 20 of this chapter.

(b) Before public disclosure of a report, FDA will delete from the report:

(1) Any information that constitutes trade secret or confidential commercial or financial information under § 20.61 of this chapter; and

(2) Any personnel, medical, or similar information, including the serial numbers of implanted devices, which would constitute a clearly unwarranted invasion of personal privacy under § 20.63 of this chapter or 5 U.S.C. 552(b)(6); provided, that except for the information under § 20.61 of this chapter or 5 U.S.C. 552(b)(4), FDA will disclose to a patient who requests a report all the information in the report concerning that patient.

PART 807—ESTABLISHMENT REGISTRATION AND DEVICE LISTING FOR MANUFACTURERS AND INITIAL IMPORTERS OF DEVICES

Subpart A—General Provisions

Subpart B—Procedures for Device Establishments

Subpart C—Registration Procedures for Foreign Device Establishments

Subpart D—Exemptions

Subpart E—Premarket Notification Procedures

AUTHORITY: 21 U.S.C. 321, 331, 351, 352, 360, 360c, 360e, 360i, 360j, 371, 374, 381, 393; 42 U.S.C. 264, 271.

SOURCE: 42 FR 42526, Aug. 23, 1977, unless otherwise noted.

Subpart A—General Provisions

§ 807.3 Definitions.

(a) *Act* means the Federal Food, Drug, and Cosmetic Act.

(b) *Commercial distribution* means any distribution of a device intended for human use which is held or offered for sale but does not include the following:

(1) Internal or interplant transfer of a device between establishments within the same parent, subsidiary, and/or affiliate company;

(2) Any distribution of a device intended for human use which has in effect an approved exemption for investigational use under section 520(g) of the act and part 812 of this chapter;

(3) Any distribution of a device, before the effective date of part 812 of this chapter, that was not introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, and that is classified into class III under section 513(f) of the act: *Provided,* That the device is intended solely for investigational use, and under section 501(f)(2)(A) of the act the device is not